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UNCLAS SECTION 01 OF 02 ANKARA 000971

SIPDIS

DEPT FOR EB/TPP/MTA/IPE - SWILSON/JURBAN AND EUR/SE
DEPT PASS USTR FOR JCHOE-GROVES
DEPT PASS LIBRARY OF CONGRESS FOR STEPP
DEPT PASS USPTO FOR JURBAN AND EWU
USDOC FOR ITA/MAC/DDEFALCO AND JBOGER

E.O. 12958: N/A

TAGS: [ETRD](#) [KIPR](#) [TU](#)

SUBJECT: Special 301 - Recommendation to Continue
Turkey's Priority Watch List Status (SBU)

Ref: (A) State 23950 (B) Ankara 394 (C) Ankara 839

(D) Ankara 941 (E) Ankara 939

Summary

1. (SBU) The GOT has taken a number of steps in the last year to improve intellectual property protection, especially for copyright owners. However, Turkey has not implemented fully TRIPS-consistent data exclusivity protection, and piracy and counterfeiting rates remain high. Embassy recommends maintaining Turkey on the Priority Watch List in the 2005 Special 301 Review, and continuing to engage the GOT with a view to enhancing intellectual property protection. End Summary.

Pharmaceuticals

2. (U) Citing concerns on data exclusivity and patent linkage, the Pharmaceuticals Research and Manufacturers Association (PhRMA) claimed IP-related losses of USD 887 million - 20 percent of sales in Turkey, up sharply from USD 600 million last year, and from much lower estimates in previous years. Describing serious non-IP problems with respect to Turkish price controls and reimbursement system reforms, PhRMA recommended elevating Turkey to Priority Foreign Country status.

3. (U) Embassy notes that data exclusivity comprises only USD 146 million of PhRMA's estimated damages. It is not clear what patent-related damages are represented by the remaining USD 741 million claimed by PhRMA. We have requested further clarification from PhRMA of the causes of these additional lost sales.

4. (U) The GOT introduced limited data exclusivity protection in a regulation issued by the Health Ministry in January 2005. Retroactive application is limited to original products licensed in a Customs Union country after January 1, 2001 for which no generic manufacturers have applied for licenses in Turkey. The term of exclusivity is limited to the duration of the drug patent. The six-year term of protection starts on the date of licensing in an EU Customs Union country, implying a shorter term of protection because of the length of the marketing approval process in Turkey (ref B).

5. (SBU) On the issue of patent linkage, the Health Ministry recently told us that a coordination mechanism has been established between the Turkish Patent Institute (TPI) and the Ministry to prevent generic applications from being filed for drugs with a valid patent (ref C). However, TPI sources subsequently advised that the Health Ministry has asked for a list of patented medicines, but that beyond this, no formal coordination mechanism exists. To our knowledge, the Health Ministry has not approved a patent-infringing copy of Zyprexa, though at least one application has been in its "final" stages for some time.

6. (SBU) While the data exclusivity regulation is inadequate, it does represent a significant step forward, given that the GOT had previously resisted implementation before the end of 2007. GOT officials have indicated that the regulation is not set in stone (ref C) and indeed the GOT is still engaged in a dialogue with the EC in the context of the Trade Barrier Review. However, we believe the Turks will continue to resist broadening the scope of retroactivity because the GOT believes it cannot legally do so in cases where there is already a generic application pending. Turkey is also likely to insist on terminating data exclusivity protection upon patent expiration so long as EU members are permitted by relevant directives to do this. It is post's understanding that EC Directive 2004/27 delinking patent and data exclusivity terms will not be mandatory

for EU members until late 2005.

17. (SBU) Embassy will continue to raise the issue of fairness for research-based companies in the Turkish pricing system and in reimbursement reform. Given the fiscal constraints imposed by Turkey's reform program and the overarching U.S. priority of reinforcing Turkey's recovery from financial crisis, we need to ensure that our message on pricing and reimbursement is framed in terms of fair treatment for innovators rather than opposition to the GOT's efforts to seek cost-savings.

Copyright, Trademarks and Other IP Issues

18. (U) Both the International Intellectual Property Alliance (IIPA) and the International AntiCounterfeiting Coalition (IACC) recommend that Turkey remain on the Watch List. They point to continued high levels of piracy and counterfeiting, and call on the GOT to improve enforcement. IIPA estimates industry losses in Turkey at USD 187 million.

19. (U) Turkey has taken a number of significant positive steps in copyright enforcement in the last year. These include:

-- Legislation banning street sales of all copyright products, leading to effective sweeps in major Turkish markets;

-- The first deterrent sentences we are aware of imposed on pirates, including large fines and imprisonment;

-- A Finance Ministry circular on investigating and prosecuting convicted pirates for tax evasion;

-- A Culture and Tourism Ministry computerized system to license vendors and other commercial users of copyright products nationwide;

Further information on these measures is provided ref D.

110. (U) Overall, Embassy believes that the GOT is making a good faith effort to improve enforcement of copyright and will continue to do so. However, we have not seen the same focus on curbing trademark counterfeiting.

111. (U) In 2004, Turkey published its first Plant Variety Protection (PVP) Law. However, at least one subsidiary of a U.S. seed company has been unable to obtain protection for its commercial seed under this new law.

Comment/Recommendation

112. (SBU) The new data exclusivity regulations, stepped up copyright enforcement and deterrent sentences represent more progress than we have seen in several years on intellectual property protection. At the same time, serious deficiencies continue in the pharmaceuticals, copyright and trademark areas. Raising Turkey to the Priority Watch List in 2004 may have played a role in prodding the GOT to making some of the improvements we have seen. Although there is a case for returning Turkey to the Watch List in 2005, Embassy suggests that, on balance, maintaining Priority Watch List status is preferable because it should generate pressure on the GOT to do more. Embassy will continue to seek appropriate opportunities to deliver our message on intellectual property, including in the Trade and Investment Framework Agreement (TIFA) meetings due to be hosted by the GOT. In this regard, we recommend that USTR correspond with its Turkish counterpart, the Foreign Trade Undersecretariat, to reiterate our interest in scheduling a TIFA meeting in the near future.

Edelman